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DOCKET NO.: B0801.70256US01

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Pier et al. 10/712,391

Serial No.: Confirmation No.:

8225

Filed:

November 12, 2003

For:

METHODS AND PRODUCTS FOR TREATING STAPHYLOCOCCAL

**INFECTIONS** 

Examiner:

Not Yet Assigned

Art Unit:

1645

## CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 23<sup>rd</sup> day of May, 2005.

Krustm Ketteled Kristin J. Ketella

### MAIL STOP AMENDMENT

Commissioner For Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- Information Disclosure Statement
- PTO Form 1449 with cited references
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit. Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted, Pier et al., Applicant

By:

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Docket No.: B0801.70256US01

Date: May 2, 2005

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Kristin J. Ketelhut

### MAIL STOP AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

# STATEMENT FILED PURSUANT TO THE DUTY OF DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

# PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing date of a first Office Action on the merits in the above-identified case.

No fee or certification is required.

Serial No.: 10/712,391 -2- Art Unit: 1645

Conf. No.: 8225

### PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

| Docket No.      | Serial No. | Filing Date    | Inventor(s) |
|-----------------|------------|----------------|-------------|
| B0801.70300US01 | 11/111,688 | April 21, 2005 | Pier et al. |

<sup>\*</sup>a copy of this reference is not provided as the Office hereby waives the requirement under 37 CFR 1.98(a)(2)(iii) for submitting a copy of each cited U.S. patent application filed after June 30, 2003 and for applications filed before June 30, 2003, or that entered the national stage before June 30, 2003, if they are scanned to Image File Wrapper system and are available on Private PAIR.

The Applicant would like to bring to the Examiner's attention the enclosed search report from a corresponding International or Foreign National Application.

| Docket No.      | Serial No.     | Mailing Date   | Type of Communication(s)          |
|-----------------|----------------|----------------|-----------------------------------|
| B0801.70256WO00 | PCT/US03/36371 | April 13, 2005 | Invitation to Pay Additional Fees |

## PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

- 1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
- 2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
- 3. The citations for the information be printed on any patent which issues from this application.

- 3 -Art Unit: 1645 Serial No.: 10/712,391

Conf. No.: 8225

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted, Pier et al., Applicant

Umuwan

Maria A. Trevisan, Reg. No. 48,207 Wolf, Greenfield & Sacks, P.C. 600 Atlantic Avenue Boston, Massachusetts 02210-2206

Telephone: (617) 646-8000

Docket No.: B0801.70256US01

Date: May 23, 2005

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FORM PTO-1449/A and B (Modified)

Sheet

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

APPLICATION NO.: 10/712,391

ATTY. DOCKET NO.: B0801.70256US01

FILING DATE: November 12, 2003

CONFIRMATION NO.: 8225

APPLICANT:

Pier et al.

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GROUP ART UNIT: 1645

EXAMINER:

Not Yet Assigned

U.S. PATENT DOCUMENTS

|                        | A TRE       |                   | 0.3.             | PATENT DOCUMENTS                                |  |  |
|------------------------|-------------|-------------------|------------------|---|--|--|
| Examiner's<br>Initials | Cite<br>No. | U.S. Patent Docur | ment  Kind  Code | Name of Patentee or Applicant of Cited Document | Date of Publication or of issue of Cited Document MM-DD-YYYY |  |
| A1                     |             | 4,197,290         | 0000             | Yoshida   | 04-08-1980   |  |
| ·                      | A2          | 4,285,936         |                  | Pier et al.                                     | 08-25-1981   |  |
|                        | A3          | 4,443,549         |                  | Sadowski  | 04-17-1984   |  |
|                        | A4          | 4,578,458         |                  | Pier  | 03-25-1986   |  |
|                        | A5          | 4,652,448         |                  | Sadowski  | 03-24-1987   |  |
|                        | A6          | 4,786,592         |                  | Deal et al.                                     | 11-22-1988   |  |
|                        | A7          | 4,789,735         |                  | Frank et al.                                    | 12-06-1988   |  |
|                        | A8          | 4,795,803         |                  | Lindberg et al.                                 | 01-03-1989   |  |
|                        | A9          | 4,830,852         |                  | Marburg et al.                                  | 05-16-1989   |  |
|                        | A10         | 4,859,449         | <del></del>      | Mattes  | 08-22-1989   |  |
| •                      | A11         | 4,879,272         |                  | Shimoda et al.                                  | 11-07-1989<br>02-20-1990                                     |  |
|                        | A12         | 4,902,616         |                  | Fournier et al.                                 |  |  |
|                        | A13         | 5,055,455         | 1                | Pier  | 10-08-1991   |  |
|                        | A14         | 5,362,754         |                  | Raad et al.                                     | 11-08-1994<br>11-22-1994                                     |  |
| •                      | A15         | 5,366,505         |                  | Farber  |  |  |
|                        | A16         | 5,571,511         |                  | Fischer   | 11-05-1996   |  |
| •                      | A17         | 5,589,591         |                  | Lewis   | 12-31-1996   |  |
|                        | A18         | 5,688,516         |                  | Raad et al.                                     | 11-18-1997   |  |
|                        | A19         | 5,718,694         |                  | Rupp  | 02-17-1998   |  |
|                        | A20         | 5,830,539         |                  | Yan et al.                                      | 11-03-1998   |  |
|                        | A21         | 5,866,140         |                  | Fattom et al.                                   | 02-02-1999   |  |
|                        | A22         | 5,980,910         |                  | Pier  | 11-09-1999   |  |
|                        | A23         | 5,989,542         |                  | Pier et al.                                     | 11-23-1999   |  |
|                        | A24         | 6,245,735         | B1               | Pier  | 06-12-2001   |  |
|                        | A25         | 6,399,066         | B1               | Pier  | 06-04-2002   |  |
|                        | A26_        | 6,743,431         | B2               | Pier  | 06-01-2004   |  |
|                        | A27         | 2002-0119166      | Al               | Pier et al.                                     | 08-29-2002   |  |
|                        | A28         | 2003-0124631      | A1               | Pier et al.                                     | 07-03-2003   |  |
|                        | A29         | 2004-0091494      | Al               | Pier et al.                                     | 05-13-2004   |  |
|                        | A30         | 2004-0175731      | A1               | Pier et al.                                     | 09-09-2004   |  |
|                        | A31         | 2005-0025775      | A1               | Pier et al.                                     | 02-03-2005   |  |

### FOREIGN PATENT DOCUMENTS

| Examiner's | Cite | Foreign Patent Document |           | nent         | Name of Patentee or Applicant of Cited | Date of<br>Publication of | Translation |
|------------|------|-------------------------|-----------|--------------|--|---------------------------|-------------|
| Initials   | No.  | Office/<br>Country      | Number    | Kind<br>Code | Document<br>(not necessary)            | Cited Document MM-DD-YYYY | (Y/N)       |
|            | Bl   | EP                      | 0 302 781 | A1           | Institut Pasteur                       | 02-08-1989                | Y- Abstr.   |

| FORM PTO-1449/A and B (Modified)                 |              |  |                      | APPLICATION NO.: | 10/712,391      | ATTY. DOCKET NO.  | : B0801.70256US01 |
|--|--------------|--|----------------------|------------------|-----------------|-------------------|-------------------|
| INFORMATION DISCLOSURE<br>STATEMENT BY APPLICANT |              |  | FILING DATE: Nov     | ember 12, 2003   | CONFIRMATION NO | D.: 8225          |                   |
|  |              |  | APPLICANT:           | Pier et al.      |                 |                   |                   |
|  |              |  | CROUD ART I DUT.     | 1645             | EXAMINER:       | Not Yet Assigned  |                   |
| Sheet  | Sheet 2 of 7 |  | GROUP ART UNIT: 1645 |                  | EAAMINEK:       | Not 1 et Assigned |                   |

| Examiner's | Cite | For                | eign Patent Docum | ent          | Name of Patentee or Applicant of Cited | Date of<br>Publication of | Translation |
|------------|------|--------------------|-------------------|--------------|--|---------------------------|-------------|
| Initials   | No.  | Office/<br>Country | Number            | Kind<br>Code | Document<br>(not necessary)            | Cited Document MM-DD-YYYY | (Y/N)       |
| <u> </u>   | B2   | EP                 | 0 694 309         | A2           | Kitasato Institute                     | 10-31-1996                |             |
|            | B3   | FR                 | 2 410 043         | A1           | Yoshida                                | 06-22-1979                | Y – Abstr.  |
|            | B4   | FR                 | 2 581 877         | A1           | Universite Catholique de Louvain       | 11-21-1986                | Y – Abstr.  |
|            | B5   | FR                 | 2 640 628         | A1           | Commissariat A L'Energie Atomique      | 12-16-1988                | Y – Abstr.  |
| -          | B6   | GB                 | 2 009 771         | Α            | Yoshida                                | 06-20-1979                |             |
|            | В7   | WO                 | 85/05037          | <b>A</b> 1   | Syntex, AB                             | 11-21-1985                |             |
|            | В8   | WO                 | 86/02358          | Al           | Technology License Company Limited     | 04-24-1986                |             |
|            | В9   | WO                 | 88/02028          | A1           | Technology License Company Limited     | 03-24-1988                |             |
|            | B10  | WO                 | 89/04873          | A1           | University of North Carolina           | 06-01-1989                |             |
|            | B11  | WO                 | 90/03398          | A1           | Brigham and Women's Hospital           | 04-05-1990                |             |
|            | B12  | WO                 | 90/06696          | A2           | Praxis Biologics, Inc.                 | 06-28-1990                |             |
|            | B13  | WO                 | 93/01276          | A1           | Smithkline Beecham Corporation         | 01-21-1993                |             |
|            | B14  | WO                 | 93/09811          | A1           | Univax Biologics, Inc.                 | 05-27-1993                |             |
|            | B15  | WO                 | 93/19373          | A1           | Fischer                                | 09-30-1993                |             |
|            | B16  | WO                 | 94/15640          | <b>A</b> 1   | Gristina                               | 07-21-1994                |             |
|            | B17  | WO                 | 98/52605          | A1           | Sumitomo Pharmaceuticals Company, Ltd  | 11-26-1998                |             |
|            | B18  | WO                 | 00/35504          | A1           | SCA Hygiene Products Zeist B.V.        | 06-22-2000                |             |
| •          | B19  | WO                 | 00/03745          | A2           | Brigham and Women's Hospital           | 01-27-2000                |             |
|            | B20  | WO                 | 2004/043405       | A2           | The Brigham and Women's Hospital, Inc. | 05-27-2004                |             |
|            | B21  | wo                 | 2004/043407       | A2           | The Brigham and Women's Hospital, Inc. | 05-27-2004                |             |

# OTHER ART — NON PATENT LITERATURE DOCUMENTS

| Examiner's<br>Initials | Cite<br>No | Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.                               |  |  |  |  |  |  |
|------------------------|------------|---|--|--|--|--|--|--|
|                        | C5         | GENBANK Submission; NIH/NCBI, Accession No. BA000018; Kuroda et al.; October 22, 2004 (last submission).  |  |  |  |  |  |  |
|                        | C6         | [No Author Listed] ATCC Catalogue website 2001; ATCC Number 35984.  |  |  |  |  |  |  |
|                        | C7         | [No Author Listed] ATCC Catalogue: Bacteria and Bacteriophages; 1992; 18th Edition; p301.   |  |  |  |  |  |  |
|                        | C8         | AMMENDOLIA et al., Slime production and expression of the slime-associated antigen by staphylococcal clinical isolates. J Clin Microbiol. 1999 Oct;37(10):3235-8.   |  |  |  |  |  |  |
|                        | C9         | BARSHAM et al., Detection of antibodies to Staphylococcus epidermidis in infected total hip replacements by an enzyme linked immunosorbent assay. J Clin Pathol. 1985 Jul;38(7):839-40.   |  |  |  |  |  |  |
| •                      | C10        | BERNSTEIN, et al., Antibody coated bacteria in otitis media with effusions. Ann Otol Rhinol Laryngol Suppl. 1980 May-Jun;89(3 Pt 2):104-9. Abstract only.   |  |  |  |  |  |  |
|                        | C11        | CAPEK et al., Chapters 22: Carbohydrates and Chapter 23: Polysaccharides. in Journal of Chromatography Journal Library – Volume 3: Liquid Column Chromatography, A Survey of Modern Technicques and Applications. Deyl et al., eds. Elsevier Scientific Publishing Company: New York, 1975. p465-528. |  |  |  |  |  |  |
|                        | C12        | CHANTER, Partial purification and characterization of two non K99 mannose-resistant haemagglutinins of Escherichia coli B41. J Gen Microbiol. 1983 Jan;129(1):235-43.   |  |  |  |  |  |  |

| FORM PTO-1449/A and B (Modified) |          |                      |                 | APPLICATION NO.                                     | : 10/712,391 | ATTY. DOCKET     | ATTY. DOCKET NO.: B0801.70256US01 |  |  |
|----------------------------------|----------|----------------------|-----------------|---|--------------|------------------|-----------------------------------|--|--|
| INFORMATION DISCLOSURE           |          |                      | FILING DATE: No | LING DATE: November 12, 2003 CONFIRMATION NO.: 8225 |              | NO.: 8225        |                                   |  |  |
|                                  | EMENT BY |                      |                 | APPLICANT:  | Pier et al.  |                  |                                   |  |  |
|                                  |          |                      | GROUP ART UNIT  | 1645  | EXAMINER:    | Not Yet Assigned |                                   |  |  |
| Sheet 3 of 7                     |          | GROUP ART UNIT: 1045 |                 | EAAMINER. Not let Assigned                          |              |                  |                                   |  |  |

| Examiner's<br>Initials                         | Cite<br>No | Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published. | Translation<br>(Y/N) |
|--|------------|---|----------------------|
|  | C13        | CHEN et al., Characterization and biological properties of chemically deglycosylated human  |                      |
|  | 1013       | chorionic gonadotropin. Role of carbohydrate moieties in adenylate cyclase activation. J Biol Chem.   |                      |
|  |            | 1982 Dec 10;257(23):14446-52.   |                      |
|  | C14        | CHRISTENSEN et al., Adherence of slime-producing strains of Staphylococcus epidermidis to   |                      |
|  |            | smooth surfaces. Infect Immun. 1982 Jul;37(1):318-26.   |                      |
|  | C15        | CHU et al., Preparation, characterization, and immunogenicity of conjugates composed of the O-  |                      |
|  |            | specific polysaccharide of Shigella dysenteriae type 1 (Shiga's bacillus) bound to tetanus toxoid.  |                      |
|  | İ          | Infect Immun. 1991 Dec;59(12):4450-8.   |                      |
|  | C16        | CONLON et al., icaR encodes a transcriptional repressor involved in environmental regulation of ica   |                      |
|  | ·          | operon expression and biofilm formation in Staphylococcus epidermidis. J Bacteriol. 2002  |                      |
|  |            | Aug;184(16):4400-8.   |                      |
|  | C17        | CONLON et al., Regulation of icaR gene expression in Staphylococcus epidermidis. FEMS   |                      |
|  |            | Microbiol Lett. 2002 Nov 5;216(2):171-7.  |                      |
|  | C18        | CRAMTON et al., The intercellular adhesion (ica) locus is present in Staphylococcus aureus and is   |                      |
|  |            | required for biofilm formation. Infect Immun. 1999 Oct;67(10):5427-33.  |                      |
|  | C19        | DOBRIN, et al., The role of complement, immunoglobulin and bacterial antigen in coagulase-  |                      |
|  |            | negative staphylococcal shunt nephritis. Am J Med. 1975 Nov;59(5):660-73. Abstract only.  |                      |
| -  | C20        | ELDER et al., Characterization of monoclonal antibodies specific for adhesion: isolation of an  |                      |
| •  | ·          | adhesin of Streptococcus sanguis FW213. Infect Immun. 1986 Nov;54(2):421-7.   |                      |
|  | C21        | ESPERSEN, et al., Solid-phase radioimmunoassay for IgG antibodies to Staphylococcus epidermidis.  |                      |
|  |            | Use in serious coagulase-negative staphylococcal infections. Arch Intern Med. 1987 Apr;147(4):689-  |                      |
| •  |            | 93. Abstract only.  |                      |
|  | C22        | ESPERSEN, et al., Enzyme-linked immunosorbent assay for detection of Staphylococcus   |                      |
|  |            | epidermidis antibody in experimental S. epidermidis endocarditis. J Clin Microbiol. 1986  |                      |
|  |            | Feb;23(2):339-42.   |                      |
| <u>.                                      </u> | C23        | FATTOM et al., Synthesis and immunologic properties in mice of vaccines composed of   |                      |
|  |            | Staphylococcus aureus type 5 and type 8 capsular polysaccharides conjugated to Pseudomonas  |                      |
|  | <u> </u>   | aeruginosa exotoxin A. Infect Immun. 1990 Jul;58(7):2367-74.  |                      |
|  | C24        | FATTOM et al., Effect of conjugation methodology, carrier protein, and adjuvants on the immune  |                      |
| _  |            | response to Staphylococcus aureus capsular polysaccharides. Vaccine. 1995 Oct;13(14):1288-93.   |                      |
| •  | C25        | FERREIROS et al., Purification and partial characterization of a K99-antigen associated adhesin in  |                      |
|  |            | Escherichia coli (637 strain). Rev Esp Fisiol. 1983 Mar;39(1):45-50.  | L                    |
|  | C26        | FOURNIER et al., Purification and characterization of Staphylococcus aureus type 8 capsular   |                      |
|  |            | polysaccharide. Infect Immun. 1984 Jul;45(1):87-93.   |                      |
|  | C27        | GERKE et al., Characterization of the N-acetylglucosaminyltransferase activity involved in the  |                      |
|  |            | biosynthesis of the Staphylococcus epidermidis polysaccharide intercellular adhesin. J Biol Chem.   |                      |
|  | <u> </u>   | 1998 Jul 17;273(29):18586-93.   |                      |
|  | C28        | GRAY et al., Effect of extracellular slime substance from Staphylococcus epidermidis on the human   |                      |
|  |            | cellular immune response. Lancet. 1984 Feb 18;1(8373):365-7.  |                      |
| •  | C29        | HEILMANN et al., Molecular basis of intercellular adhesion in the biofilm-forming Staphylococcus  |                      |
|  |            | epidermidis. Mol Microbiol. 1996 Jun;20(5):1083-91.   |                      |
|  | C30        | HEILMANN et al., Characterization of Tn917 insertion mutants of Staphylococcus epidermidis  |                      |
|  | 1          | affected in biofilm formation. Infect Immun. 1996 Jan;64(1):277-82.   | <u> </u>             |
|  | C31        | HOGT et al., Cell surface characteristics of coagulase-negative staphylococci and their adherence to  |                      |
|  |            | fluorinated poly(ethylenepropylene). Infect Immun. 1986 Jan;51(1):294-301.  |                      |
|  | C32        | ICHIMAN et al., The relationship of capsular-type of Staphylococcus epidermidis to virulence and  |                      |
|  | 1          | induction of resistance in the mouse. J Appl Bacteriol. 1981 Oct;51(2):229-41.  |                      |

| FORM PTO  | )_1449/A and R () | Andifie. | d)   | APPLICATION NO.  | : 10/712,391             | ATTY. DOCKET N | NO.: B0801.70256US01 |
|---|-------------------|----------|------|------------------|--------------------------|----------------|----------------------|
| FORM PTO-1449/A and B (Modified)  INFORMATION DISCLOSURE STATEMENT BY APPLICANT |                   |          |      | FILING DATE: Nov | vember 12, 2003          | CONFIRMATION   | NO.: 8225            |
|   |                   |          |      | APPLICANT:       | Pier et al.              |                |                      |
|   |                   |          |      | GROUP ART UNIT:  | 1645                     | EXAMINER:      | Not Yet Assigned     |
| Sheet   | Sheet 4 of 7      |          | 1045 |                  | LAMININER. NOT TOUTISHEN |                |                      |

| Examiner's<br>Initials | No (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number publisher, city and/or country where published. |   |  |  |  |  |  |
|------------------------|---|---|--|--|--|--|--|
|                        | C33   | ICHIMAN et al., Induction of resistance with heat-killed unencapsulated strains of Staphylococcus     |  |  |  |  |  |
|                        |   | epidermidis against challenge with encapsulated strains of Staphylococcus epidermidis. Microbiol      |  |  |  |  |  |
|                        |   | Immunol. 1989;33(4):277-86.   |  |  |  |  |  |
| *****                  | C34   | ICHIMAN et al., Relation of human serum antibody against Staphylococcus epidermidis cell surface      |  |  |  |  |  |
|                        |   | polysaccharide detected by enzyme-linked immunosorbent assay to passive protection in the mouse. J    |  |  |  |  |  |
|                        |   | Appl Bacteriol. 1991 Aug;71(2):176-81.  |  |  |  |  |  |
|                        | C35   | ICHIMAN et al., Specificity of monclonal antibodies against an encapsulated strain of                 |  |  |  |  |  |
|                        |   | staphylococcus epidermids. in The Staphylococci, Zbl Bakt. 1991;Suppl 21:150-2.                       |  |  |  |  |  |
|                        | C36   | JEFFERSON et al., Identification of a 5-nucleotide sequence that controls expression of the ica locus |  |  |  |  |  |
|                        |   | in Staphylococcus aureus and characterization of the DNA-binding properties of IcaR. Mol              |  |  |  |  |  |
|                        |   | Microbiol. 2003 May;48(4):889-99.   |  |  |  |  |  |
|                        | C37   | JEFFERSON et al., The teicoplanin-associated locus regulator (TcaR) and the intercellular adhesin     |  |  |  |  |  |
|                        |   | locus regulator (IcaR) are transcriptional inhibitors of the ica locus in Staphylococcus aureus. J    |  |  |  |  |  |
|                        |   | Bacteriol. 2004 Apr; 186(8):2449-56.  |  |  |  |  |  |
|                        | C38   | JOHNSON et al., Interference with granulocyte function by Staphylococcus epidermidis slime. Infect    |  |  |  |  |  |
|                        |   | Immun. 1986 Oct;54(1):13-20.  |  |  |  |  |  |
|                        | C39   | KELLY-QUINTOS et al., Biological Characterization of Fully Human Monoclonal Antibodies to             |  |  |  |  |  |
|                        |   | Staphylococcal Surface Polysaccharide PNAG. Abstracts of the 104th General Meeting of the             |  |  |  |  |  |
|                        |   | American Society for Microbiology. Am Soc Microbiol. 2004 May; abstract A-63. Abstract and            |  |  |  |  |  |
|                        |   | corresponding presentation.   |  |  |  |  |  |
|                        | C40   | KEUTMANN et al., Evidence for a conformational change in deglycosylated glycoprotein hormones.        |  |  |  |  |  |
|                        |   | FEBS Lett. 1985 Jun 17;185(2):333-8.  |  |  |  |  |  |
|                        | C41   | KOHLER, Derivation and diversification of monoclonal antibodies. Science. 1986 Sep                    |  |  |  |  |  |
|                        |   | 19;233(4770):1281-6.  |  |  |  |  |  |
|                        | C42   | KOJIMA et al., Antibody to the capsular polysaccharide/adhesin protects rabbits against catheter-     |  |  |  |  |  |
|                        |   | related bacteremia due to coagulase-negative staphylococci. J Infect Dis. 1990 Aug;162(2):435-41.     |  |  |  |  |  |
|                        | C43   | KURODA et al., Whole genome sequencing of meticillin-resistant Staphylococcus aureus. Lancet.         |  |  |  |  |  |
|                        |   | 2001 Apr 21;357(9264):1225-40.  |  |  |  |  |  |
|                        | C44   | LEE et al., Chemical characterization and immunogenicity of capsular polysaccharide isolated from     |  |  |  |  |  |
|                        |   | mucoid Staphylococcus aureus. Infect Immun. 1987 Sep;55(9):2191-7.                                    |  |  |  |  |  |
|                        | C45   | LEE et al., Protective efficacy of antibodies to the Staphylococcus aureus type 5 capsular            |  |  |  |  |  |
|                        |   | polysaccharide in a modified model of endocarditis in rats. Infect Immun. 1997 Oct;65(10):4146-51.    |  |  |  |  |  |
|                        | C46   | LEITH et al., Purification of a Mycoplasma pneumoniae adhesin by monoclonal antibody affinity         |  |  |  |  |  |
|                        |   | chromatography. J Bacteriol. 1984 Feb;157(2):678-80.  |  |  |  |  |  |
|                        | C47   | LOCKSLEY, Chapter 94: Staphylococcal Infections. in Harrison's Principles of Internal Medicine,       |  |  |  |  |  |
|                        |   | Eleventh Edition. Braunwald et al., eds. McGraw-Hill Book Company, Inc.: New York, 1950. p537-        |  |  |  |  |  |
|                        |   | 43.   |  |  |  |  |  |
|                        | C48   | LUDWICKA et al., Investigation on extracellular slime substance produced by Staphylococcus            |  |  |  |  |  |
|                        |   | epidermidis. Zentralbl Bakteriol Mikrobiol Hyg [A]. 1984 Dec;258(2-3):256-67.                         |  |  |  |  |  |
| •                      | C49   | MACK et al., Association of biofilm production of coagulase-negative staphylococci with expression    |  |  |  |  |  |
|                        |   | of a specific polysaccharide intercellular adhesin. J Infect Dis. 1996 Oct;174(4):881-4.              |  |  |  |  |  |
|                        | C50   | MACK et al., Characterization of transposon mutants of biofilm-producing Staphylococcus               |  |  |  |  |  |
| •                      |   | epidermidis impaired in the accumulative phase of biofilm production: genetic identification of a     |  |  |  |  |  |
|                        | 1   | hexosamine-containing polysaccharide intercellular adhesin. Infect Immun. 1994 Aug;62(8):3244-53.     |  |  |  |  |  |
|                        | C51   | MACK et al., Parallel induction by glucose of adherence and a polysaccharide antigen specific for     |  |  |  |  |  |
|                        |   | plastic-adherent Staphylococcus epidermidis: evidence for functional relation to intercellular        |  |  |  |  |  |
|                        |   | adhesion. Infect Immun. 1992 May;60(5):2048-57.   |  |  |  |  |  |

| EODM DTC                         | ) 1449/4 and D (N                             | (odified)       |                  | APPLICATION NO.:                                     | 10/712,391       | ATTY. DOCKET N | ATTY. DOCKET NO.: B0801.70256US01 |  |  |
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|------------------------|------------|---|---------------------|
|                        | C52        | MACK et al., Essential functional role of the polysaccharide intercellular adhesin of Staphylococcus  |                     |
|                        |            | epidermidis in hemagglutination. Infect Immun. 1999 Feb;67(2):1004-8.   |                     |
|                        | C53        | MACK et al., Identification of three essential regulatory gene loci governing expression of   |                     |
|                        |            | Staphylococcus epidermidis polysaccharide intercellular adhesin and biofilm formation. Infect   |                     |
|                        |            | Immun. 2000 Jul;68(7):3799-807.   |                     |
|                        | C54        | MAIRA-LITRAN et al., Deacetylated-poly-N-acetyl Glucosamine (dPNAG) Polysaccharide  |                     |
|                        |            | Conjugated to Diphtheria Toxoid (DT) Confers Protection Against Multiple Strains of   |                     |
|                        |            | Staphylococcus aureus in a Murine Model of Bacteremia. Abstracts of the 104th General Meeting of  |                     |
|                        | '          | the American Society for Microbiology. Am Soc Microbiol. 2004 May; abstract D-130. Abstract and   |                     |
|                        |            | corresponding presentation.   |                     |
| <del></del>            | C55        | MAIRA-LITRAN et al., Synthesis and Immunological Properties of a Staphylococcal Deacetylated-   |                     |
|                        |            | poly-N-acetyl Glucosamine (dPNAG) Polysaccharide and Clumping Factor A (ClfA) Protein   |                     |
|                        |            | Conjugate Vaccine. Abstracts of the 104th General Meeting of the American Society for   |                     |
|                        |            | Microbiology. Am Soc Microbiol. 2004 May; abstract E-062. Abstract and corresponding  |                     |
|                        |            | presentation.   |                     |
|                        | C56        | McKENNEY et al., Broadly protective vaccine for Staphylococcus aureus based on an in vivo-  |                     |
|                        | Ì          | expressed antigen. Science. 1999 May 28;284(5419):1523-7.   |                     |
|                        | C57        | McKENNEY et al., Vaccine potential of poly-1-6 beta-D-N-succinylglucosamine, an   |                     |
|                        |            | immunoprotective surface polysaccharide of Staphylococcus aureus and Staphylococcus epidermidis.  |                     |
|                        |            | J Biotechnol. 2000 Sep 29;83(1-2):37-44.  |                     |
|                        | C58        | MELEAN et al., Toward the automated solid-phase synthesis of oligoglucosamines: systematic  |                     |
|                        |            | evaluation of glycosyl phosphate and glycosyl trichloroacetimidate building blocks. Carbohydr Res.  |                     |
|                        |            | 2002 Nov 19;337(21-23):1893-916.  |                     |
|                        | C59        | MILSTEIN, From antibody structure to immunological diversification of immune response. Science.   | ·                   |
|                        |            | 1986 Mar 14;231(4743):1261-8.   |                     |
|                        | C60        | MOCH et al., Isolation and characterization of the alpha-sialyl-beta-2,3-galactosyl-specific adhesin  |                     |
|                        |            | from fimbriated Escherichia coli. Proc Natl Acad Sci U S A. 1987 May;84(10):3462-6.   |                     |
|                        | C61        | MOREAU et al., Structure of the type 5 capsular polysaccharide of Staphylococcus aureus.  |                     |
|                        |            | Carbohydr Res. 1990 Jul 1;201(2):285-97.  |                     |
|                        | C62        | MULLER et al., Occurrence of capsular polysaccharide/adhesin among clinical isolates of coagulase-  |                     |
|                        |            | negative staphylococci. J Infect Dis. 1993 Nov;168(5):1211-8.   |                     |
|                        | C63        | NAGY et al., Multi-adhesin vaccines for the protection of the neonatal piglet against "E. coli"   |                     |
|                        | <u> </u>   | infections. Dev Biol Stand. 1983;53:189-97.   |                     |
|                        | C64        | NAKANO, et al., Polyclonal antibody production in murine spleen cells induced by Staphylococcus.  |                     |
|                        |            | Microbiol Immunol. 1980;24(10):981-94. Abstract only.   |                     |
|                        | C65        | OHSHIMA et al., Cell surface antigen of encapsulated Staphylococcus epidermidis ATCC 31432. J   |                     |
|                        | <u> </u>   | Clin Microbiol. 1987 Jul;25(7):1338-40.   |                     |
|                        | C66        | OHSHIMA et al., Protection inducing antigen of an encapsulated staphylococcus epidermis SE-10. in   |                     |
|                        |            | The Staphylococci, Zbl Bakt. 1991;Suppl 21:279-80.  |                     |
| •                      | C67        | ORSKOV et al., An adhesive protein capsule of Escherichia coli. Infect Immun. 1985 Jan;47(1):191-   |                     |
|                        |            | 200.  |                     |
|                        | C68        | PETERS et al., Biology of s.epidermidis extracellular slime. in The Staphylococci, Zbl Bakt.  |                     |
| <u> </u>               |            | 1987;Suppl 16:15-33.  |                     |
|                        | C69        | QUIE et al., Coagulase-negative staphylococcal adherence and persistence. J Infect Dis. 1987  |                     |
|                        |            | Oct;156(4):543-7.   |                     |
|                        | C70        | ROGEMOND et al., Lectinlike adhesins in the Bacteroides fragilis group. Infect Immun. 1986  |                     |
|                        | 1          | Jul;53(1):99-102.   |                     |

| FORM PTO 1440/A and P (Madified)   |   |    |                                | APPLICATION NO.: 10/712,391 |                        | ATTY. DOCKET NO.: B0801.70256US01 |                    |  |
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| FORM PTO-1449/A and B (Modified)  INFORMATION DISCLOSURE  STATEMENT BY APPLICANT |   |    | FILING DATE: November 12, 2003 |                             | CONFIRMATION NO.: 8225 |                                   |                    |  |
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|------------------------|------------|---|--|
| _                      | C71        | RUPP et al., Characterization of the importance of polysaccharide intercellular   |  |
|                        | 0/1        | adhesin/hemagglutinin of Staphylococcus epidermidis in the pathogenesis of biomaterial-based  |  |
|                        |            | infection in a mouse foreign body infection model. Infect Immun. 1999 May;67(5):2627-32.  |  |
|                        | C72        | RUPP et al., Characterization of Staphylococcus epidermidis polysaccharide intercellular  |  |
|                        | 1 0/2      | adhesin/hemagglutinin in the pathogenesis of intravascular catheter-associated infection in a rat   |  |
|                        |            | 1 0   |  |
|                        | 672        | model. Infect Immun. 1999 May;67(5):2656-9.   |  |
|                        | C73        | SANFORD et al., Detection of staphylococcal membrane receptors on virus-infected cells by direct  | 1  |
|                        | 054        | adhesin overlay. Infect Immun. 1986 Jun;52(3):671-5.  | <del></del>                                      |
|                        | C74        | SCHUMACHER-PERDREAU et al., Comparative analysis of a biofilm-forming Staphylococcus  |  |
|                        | ŀ          | epidermidis strain and its adhesion-positive, accumulation-negative mutant M7. FEMS Microbiol   |  |
| -                      |            | Lett. 1994 Mar 15;117(1):71-8.  |  |
|                        | C75        | SOMPOLINSKY et al., Encapsulation and capsular types in isolates of Staphylococcus aureus from  |  |
|                        | ļ          | different sources and relationship to phage types. J Clin Microbiol. 1985 Nov;22(5):828-34.   |  |
|                        | C76        | TAKEDA et al., Protection against endocarditis due to Staphylococcus epidermidis by immunization  |  |
|                        |            | with capsular polysaccharide/adhesin. Circulation. 1991 Dec;84(6):2539-46.  | igspace  |
|                        | C77        | THOMAS et al., Enzyme-linked lectinsorbent assay measures N-acetyl-D-glucosamine in matrix of   |  |
|                        |            | biofilm produced by Staphylococcus epidermidis. Curr Microbiol. 1997 Oct;35(4):249-54.  |  |
|                        | C78        | TOJO et al., Isolation and characterization of a capsular polysaccharide adhesin from Staphylococcus  |  |
|                        |            | epidermidis. J Infect Dis. 1988 Apr;157(4):713-22.  |  |
|                        | C79        | TOLLERSRUD et al., Genetic and serologic evaluation of capsule production by bovine mammary   |  |
|                        |            | isolates of Staphylococcus aureus and other Staphylococcus spp. from Europe and the United States.  |  |
| •                      | 1          | J Clin Microbiol. 2000 Aug;38(8):2998-3003.   |  |
|                        | C80        | VERSHIGORA et al., Secretory antibodies to homologous and heterologous staphylococcal strains in  |  |
|                        |            | the colostrum of rabbits. Zh Mikrobiol Epidemiol Immunobiol. 1980;88-90. Russian.   | Y – Abst   |
|                        | C81        | VUONG et al., A crucial role for exopolysaccharide modification in bacterial biofilm formation,   |  |
|                        |            | immune evasion, and virulence. J Biol Chem. 2004 Dec 24;279(52):54881-6. Epub 2004 Oct 22.  |  |
|                        | C82        | WANG et al., The pgaABCD locus of Escherichia coli promotes the synthesis of a polysaccharide   |  |
|                        |            | adhesin required for biofilm formation. J Bacteriol. 2004 May;186(9):2724-34.   |  |
|                        | C83        | WESSELS et al., Isolation and characterization of type IV group B Streptococcus capsular  |  |
|                        |            | polysaccharide. Infect Immun. 1989 Apr;57(4):1089-94.   |  |
|                        | C84        | WRAY et al., Identification and characterization of a uroepithelial cell adhesin from a uropathogenic   |  |
|                        | 00.        | isolate of Proteus mirabilis. Infect Immun. 1986 Oct;54(1):43-9.  | 1  |
|                        | C85        | YAMADA, et al., Possible common biological and immunological properties for detecting   | <u> </u>   |
|                        | 003        | encapsulated strains of Staphylococcus epidermidis. J Clin Microbiol. 1988 Oct;26(10):2167-72.  |  |
| ·                      | C86        | YOSHIDA et al., Mouse virulent strain of Staphylococcus epidermidis. Relation of antiphagocytic   |  |
|                        | 1 000      | activity to the protection-inducing antigen. Jpn J Microbiol. 1976 Jun;20(3):209-17.  |  |
|                        | C87        | YOSHIDA, et al., Immunological response to a strain of Staphylococcus epidermidis in the rabbit:  |  |
|                        | 007        | production of protective antibody. J Med Microbiol. 1978 Nov;11(4):371-7. Abstract only.  |  |
|                        | COO        | YOSHIDA et al., Cross protection between a strain of Staphylococcus epidermidis and eight other   | <del>  </del>                                    |
|                        | C88        | species of coagulase-negative staphylococci. Can J Microbiol. 1988 Jul;34(7):913-5.   |  |
|                        | 1          |   | <del>                                     </del> |
| •                      | 000        |   |  |
| •                      | C89        | YOUMANS, Staphylococci, Staphylococcal Disease, and Toxic Shock Syndrome. in The Biologic   |  |
|                        | C89        | and Clinical Basis of Infectious Diseases, Third Edition Youmans et al., eds. W.B. Saunders   |  |
| •                      |            | and Clinical Basis of Infectious Diseases, Third Edition Youmans et al., eds. W.B. Saunders Company: Philadelphia, 1985. p 618-29 and 738-9.  |  |
| •                      | C89        | and Clinical Basis of Infectious Diseases, Third Edition Youmans et al., eds. W.B. Saunders   |  |

| FORM PTO-1449/A and B (Modified) |   |    |                                | APPLICATION NO.: 10/712,391 |                        | ATTY. DOCKET NO.: B0801.70256US01 |                        |  |
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|------------------------|------------|--|---------------------|--|
|                        | C91        | ZIEBUHR et al., A novel mechanism of phase variation of virulence in Staphylococcus epidermidis: evidence for control of the polysaccharide intercellular adhesin synthesis by alternating insertion and excision of the insertion sequence element IS256. Mol Microbiol. 1999 Apr;32(2):345-56. |                     |  |

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